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PTO/SB/05 (4/98)
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Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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UTILITY PATENT APPLICATION TRANSMITTAL

(Only for new nonprovisional applications under 37 C.F.R. § 1.53(b))

Attorney Docket No.	155696-0024
First Inventor or Application Identifier	Alex Urich
Title	LOW FREQUENCY CATARACT FRAGMENTING DEVICE
Express Mail Label No.	EK341754940US

APPLICATION ELEMENTS

See MPEP chapter 600 concerning utility patent application contents

ADDRESS TO: **Assistant Commissioner for Patents, Box Patent Application, Washington, DC 20231**

1. [X] * Fee Transmittal Form *(e.g., PTO/SB/17)* *(Submit an original and a duplicate for fee processing)*
2. [X] Specification [*Total Pages* 18] *(preferred arrangement set forth below)*
   - Descriptive title of the Invention
   - Cross References to Related Applications
   - Statement Regarding Fed sponsored R & D
   - Reference to Microfiche Appendix
   - Background of the Invention
   - Brief Summary of the Invention
   - Brief Description of the Drawings *(if filed)*
   - Detailed Description
   - Claim(s)
   - Abstract of the Disclosure
3. [X] Drawing(s) *(35 U.S.C. 113)* [*Total Sheets* 2]
4. Oath or Declaration [*Total Pages* 3]
   - a. [X] Newly executed (original or copy)
   - b. [ ] Copy from a prior application (37 C.F.R. § 1.63(d)) *(for continuation/divisional with Box 16 completed)*
     - i. [ ] DELETION OF INVENTOR(S) Signed statement attached deleting inventor(s) named in the prior application, see 37 C.F.R. §§ 1.63(d)(2) and 1.33(b).

NOTE FOR ITEMS 1 & 13: IN ORDER TO BE ENTITLED TO PAY SMALL ENTITY FEES, A SMALL ENTITY STATEMENT IS REQUIRED (37 C.F.R. § 1.27), EXCEPT IF ONE FILED IN A PRIOR APPLICATION IS RELIED UPON (37 C.F.R. § 1.28).

5. [ ] Microfiche Computer Program *(Appendix)*
6. Nucleotide and/or Amino Acid Sequence Submission *(if applicable, all necessary)*
   - a. [ ] Computer Readable Copy
   - b. [ ] Paper Copy (identical to computer copy)
   - c. [ ] Statement verifying identity of above copies

ACCOMPANYING APPLICATION PARTS

7. [X] Assignment Papers (cover sheet & document(s))
8. [ ] 37 C.F.R.§3.73(b) Statement *(when there is an assignee)* [ ] Power of Attorney
9. [ ] English Translation Document *(if applicable)*
10. [ ] Information Disclosure Statement (IDS)/PTO-1449 [ ] Copies of IDS Citations
11. [ ] Preliminary Amendment
12. [X] Return Receipt Postcard (MPEP 503) *(Should be specifically itemized)*
13. [X] * Small Entity Statement(s) *(PTO/SB/09-12)* [ ] Statement filed in prior application, Status still proper and desired
14. [ ] Certified Copy of Priority Document(s) *(if foreign priority is claimed)*
15. [ ] Other: .....

16. **If a CONTINUING APPLICATION,** *check appropriate box, and supply the requisite information below and in a preliminary amendment:*

☐ Continuation ☐ Divisional ☐ Continuation-in-part (CIP) of prior application No: _____/_____

Prior application information: *Examiner* _____ *Group / Art Unit:* _____

For CONTINUATION or DIVISIONAL APPS only: The entire disclosure of the prior application, from which an oath or declaration is supplied under Box 4b, is considered a part of the disclosure of the accompanying continuation or divisional application and is hereby incorporated by reference. The incorporation can only be relied upon when a portion has been inadvertently omitted from the submitted application parts.

17. CORRESPONDENCE ADDRESS

☐ *Customer Number or Bar Code Label* *(Insert Customer No. or Attach bar code label here)* *or* ☒ *Correspondence address below*

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	Suite 400				
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Name (Print/Type)	Ben J. Yorks	*Registration No. (Attorney/Agent)*	33,609
Signature	Ben Yorks	*Date*	April 4, 2000

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STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) & 1.27(c))--SMALL BUSINESS CONCERN

Docket Number (Optional): 155696-0024

Applicant, Patentee, or Identifier: Alex Urich et al.
Application or Patent No.:
Filed or Issued:
Title: Low Frequency Cataract Fragmenting Device

I hereby state that I am
☐ the owner of the small business concern identified below
☒ an official of the small business concern empowered to act on behalf of the concern identified below:

NAME OF SMALL BUSINESS CONCERN: Circuit Tree Medical, Inc.

ADDRESS OF SMALL BUSINESS CONCERN: 22332 Madero Road, Suite F
Mission Viejo, California 92691

I hereby state that the above identified small business concern qualifies as a small business concern as defined in 13 CFR Part 121 for purposes of paying reduced fees to the United States Patent and Trademark Office. Questions related to size standards for a small business concern may be directed to: Small Business Administration, Size Standards Staff, 409 Third Street, SW, Washington, DC 20416.

I hereby state that rights under contract or law have been conveyed to and remain with the small business concern identified above with regard to the invention described in:

☒ the specification filed herewith with title as listed above
☐ the application identified above.
☐ the patent identified above.

If the rights held by the above identified small business concern are not exclusive, each individual, concern, or organization having rights in the invention must file separate statements as to their status as small entities, and no rights to the invention are held by any person, other than the inventor, who would not qualify as an independent inventor under 37 CFR 1.9(c) if that person made the invention, or by any concern which would not qualify as a small business concern under 37 CFR 1.9(d), or a nonprofit organization under 37 CFR 1.9(e).

Each person, concern, or organization having any rights in the invention is listed below.
☒ no such person, concern, or organization exists.
☐ each such person, concern, or organization is listed below

Separate statements are required from each named person, concern or organization having rights to the invention stating their status as small entities. (37 CFR 1.27)

I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

NAME OF PERSON SIGNING: Alex Urich

TITLE OF PERSON IF OTHER THAN OWNER: President

ADDRESS OF PERSON SIGNING: 22332 Madero Road, Suite F, Mission Viejo, California 92691

SIGNATURE: Alex Urich DATE: 3/30/00

Atty. Docket No. 155696-0024
Express Mail Label No. EK341754940US

UNITED STATES PATENT APPLICATION

FOR

LOW FREQUENCY CATARACT FRAGMENTING DEVICE

INVENTORS:

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Michael Curtis

PREPARED BY:

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Newport Beach, California 92660
(949) 760-0991

BACKGROUND OF THE INVENTION

1. Cross-Reference to Related Application

The present application claims benefit of U.S. Provisional Application No. 60/173,829, filed December 30, 1999.

2. Field of the Invention

The present invention relates to a control circuit for driving a transducer that is coupled to a mechanical cutting element.

3. Prior Art

The lens of a human eye may develop a cataracteous condition which affects a patients vision. Cataracteous lenses are sometimes removed and replaced in a procedure commonly referred to as phacoemulsification. Phaco procedures are typically performed with an ultrasonically driven handpiece which is used to break the lens. The broken lens is removed through an aspiration line that is coupled to the handpiece.

The handpiece has a tip which is inserted through an incision in the cornea. The handpiece typically contains a

number of ultrasonic transducers that convert electrical power into a mechanical oscillating movement of the tip. The distal end of the tip has an opening which is in fluid communication with the aspiration line. The oscillating movement of the tip will break the lens into small pieces that are then drawn into the aspiration line through the tip opening.

The handpiece is typically connected to a console that contains a power supply. The power supply provides a driving signal that drives the ultrasonic transducers. To obtain a maximum response from the ultrasonic transducers, the frequency of the driving signal is typically at, or close to, the natural frequency of the transducers. A driving signal at the natural frequency will cause the transducers to operate in a resonant mode.

It has been found that an ultrasonically driven tip will generate heat which may burn or otherwise denature the corneal tissue. The denatured tissue may affect the patients vision. Additionally, the oscillating tip creates turbulence in the surrounding fluid. The turbulent fluid can make it difficult to view the end of the tip and increase the difficulty of performing the procedure. It

would be desirable to provide an ultrasonically driven handpiece that can cut tissue but does not generate a significant amount of heat. It would also be desirable to provide a phaco handpiece that does not create a relatively large amount of turbulence during operation.

BRIEF SUMMARY OF THE INVENTION

One embodiment of the present invention is a control circuit that provides a driving signal to a transducer coupled to a mechanical cutting element. The transducer is capable of operating in a resonant mode. The driving signal contains a plurality of pulses provided in a time interval that does not cause the transducer to operate in the resonant mode.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 is an illustration of an embodiment of a tissue cutting system of the present invention;

Figure 2 is a schematic of a control circuit of the system;

Figure 3 is a graph showing a driving signal provided by the control circuit; and,

Figure 4 is schematic of an alternate embodiment of a tissue cutting system.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

In general the present invention provides a control circuit that provides a driving signal to a transducer that is coupled to a mechanical cutting element. The driving signal has a waveform such that the mechanical cutting element can cut tissue without generating heat. The driving signal contains packets of pulses separated by pauses. Each packet will have a time duration that does not induce a resonant mode of operation for the transducer. The packets do have enough energy to move the cutting element and cut tissue. It has been found that the short duration of pulses will cut tissue without generating any significant amount of heat at the cutting site. Additionally, when used in a fluid environment such as a phaco procedure it was found that the cutting element did not create as much fluid turbulence than devices of the prior art. The reduction in turbulence improves visibility for the surgeon performing the procedure.

Referring to the drawings more particularly by reference numbers, Figure 1 shows an embodiment of an ultrasonic tissue cutting system 10 of the present invention. The system 10 may include an ultrasonically

driven handpiece which has a tip 14 that can be inserted into a cornea 16. The tip 14 may also be referred to as a cutting element. The handpiece 12 may include one or more ultrasonic transducers 18 that convert electrical power into mechanical movement of the tip 14. The handpiece 12 is typically held by a surgeon who performs a surgical procedure with the system 10. By way of example, the system 10 can be used to perform a phacoemulsification procedure to break and aspirate a lens of the cornea 16.

The handpiece 12 is coupled to a pump 20 by an aspiration line 22. The pump 20 creates a vacuum pressure within the aspiration line 22. The aspiration line 22 is in fluid communication with an inner channel 24 and opening 26 in the tip 14. The vacuum pressure within the line 22 can aspirate matter from the cornea 16.

The system 10 may include a control circuit 28 that provides a driving signal to the transducers 18. The control circuit 28 may be located within a console 30 that is connected the handpiece 12. The console 30 may have input knobs or buttons 32 that allow the surgeon to vary different parameters of the system 10. The console 30 may

also have a readout display 34 that provides an indication of the power level, etc. of the system 10.

Figure 2 shows an embodiment of a control circuit 28. The control circuit 28 may include a microprocessor 36 that defines the driving signal provided to the transducers 18. The driving signal may be defined in accordance with a software and/or firmware of the system. The processor 36 may be connected to, or contain, memory 38 which contains instructions and data used to perform software to define the driving signal and operate the system 10. Although a microprocessor 36 is shown and described, it is to be understood that other elements, circuits or devices may be used to generate the driving signal.

The processor 36 may be connected to, or contain, a digital to analog (D/A) converter 40. The D/A converter 40 converts digital bits strings provided by the processor 36 to an analog signal. The D/A converter 40 may be connected to a voltage controlled oscillator (VCO) 42 that converts the analog signal to a driving signal. The frequency of the driving signal is dependent upon the amplitude of the analog signal provided from the D/A converter 40. The

driving signal may be amplified by an amplifier 44 before being provided to the transducers 18.

The transducers 18 have a natural frequency. Additionally, the transducers 18 are capable of operating in a resonant mode to provide a maximum output. The handpiece 12 may also include a horn (not shown) that mechanically amplifies the output of the transducers 18.

Figure 3 shows an example of a driving signal provided to the transducers. The driving signal may include packets of pulses separated by pauses. Each packet may have a duration short enough so that the transducers 18 do not enter a resonant mode of operation. The pulses still have enough energy to induce functional movement of the tip 14. The pauses should be of a duration to avoid resonant operation and the generation of a significant amount of heat.

For phaco handpieces with ultrasonically driven piezoelectric transducers it was found that a packet duration between 0.5-5.0 milliseconds allows the tip to effectively cut tissue without generating a significant amount of heat at the cutting site. Additionally, it was

found that a pause duration between 5-50 milliseconds provided satisfactory results.

When a phaco handpiece was tested using the above ranges, it was found that the temperature at the cutting site did not rise above 45 °C. The best results occurred with a packet duration of 0.5 milliseconds and a pause duration of 3.5 seconds for a repetition frequency of 250 hertz (Hz). Because the transducers 18 do not resonate, the effective oscillation frequency of the transducers 18 and accompanying tip 14 is equal to the repetition frequency.

It is desirable to provide a pulse frequency that is the same or close to the natural frequency of the transducers. For example, for transducers with a natural frequency of 20 KHz, it was found that a pulse frequency of 22 KHz provided satisfactory results. In general it has been found that providing short packets of pulses that do not induce resonance in the transducers provides a cutting tool that can cut tissue without generating a significant amount of heat.

While certain exemplary embodiments have been described and shown in the accompanying drawings, it is to be

understood that such embodiments are merely illustrative of and not restrictive on the broad invention, and that this invention not be limited to the specific constructions and arrangements shown and described, since various other modifications may occur to those ordinarily skilled in the art.

For example, Figure 4 shows the present invention implemented into a microkeratome 50. The microkeratome 50 is typically used to cut a flap in the cornea to perform a LASIK procedure. LASIK procedures can correct vision by ablating corneal tissue with a laser.

The microkeratome 50 includes a blade 52 that is mounted to a blade holder 54. The blade holder 54 is coupled to a motor 56 that can move the blade 52 across a cornea. The blade 52 may also be connected to transducers 58 that are connected to a control circuit 60. The control circuit 60 may provide a driving signal that causes the blade 52 to move in an oscillating manner. The oscillating motion of the blade 52 will cut tissue while the motor 56 moves the blade across a cornea. The driving signal may be the same or similar to the signal described above and shown in Fig. 3. Such a driving signal will allow the blade 52

to cut without generating heat within the tissue. The generation of heat may denature the cornea and affect the patients vision.

Additionally, the control circuit and resultant driving signal can be used to drive other tissue cutting devices.

CLAIMS

What is claimed is:

1. A circuit that is coupled to a transducer that can drive a cutting element, wherein the transducer has a natural frequency and can operate in a resonant mode, comprising:

a control circuit adapted to provide a driving signal to the transducer, said driving signal including a plurality of pulses provided in a time duration that does not induce the transducer to operate in the resonant mode.

2. The circuit of claim 1, wherein said pulses are provided in a plurality of packets that are separated by pauses.

3. The circuit of claim 1, wherein said pulses have a frequency approximately at the natural frequency of the cutting element.

4. The circuit of claim 2, wherein each packet has a time duration between 0.5 and 5 milliseconds.

5. The circuit of claim 2, wherein each pause has a time duration that prevents a generation of a significant amount of heat by the cutting element.

6. A tissue cutting device, comprising:

a cutting element;

a transducer that moves said cutting element, said transducer having a natural frequency and can operate in a resonant mode;

a control circuit that provides a driving signal to said transducer, said driving signal including a plurality of pulses provided in a time duration that does not induce said transducer to operate in the resonant mode.

7. The device of claim 6, wherein said pulses are provided in a plurality of packets that are separated by pauses.

8. The device of claim 6, wherein said pulses have a frequency approximately at the natural frequency of the driving element.

9. The device of claim 7, wherein each packet has a time duration between 0.5 and 5 milliseconds.

10. The device of claim 6, wherein the resonant mode is in an ultrasonic frequency range.

11. The device of claim 6, wherein said cutting element is a tip.

12. The device of claim 7, wherein each pause has a time duration that prevents a generation of a significant amount of heat by the cutting element.

13. A method for driving transducer that moves a cutting element, wherein the transducer has a natural frequency and can operate in a resonant mode, comprising:

transmitting a driving signal to the transducer, said driving signal including a plurality of pulses provided in a time duration that does not induce said transducer to operate in the resonant mode.

14. The method of claim 13, wherein the pulses are provided in a plurality of packets each separated by a pause.

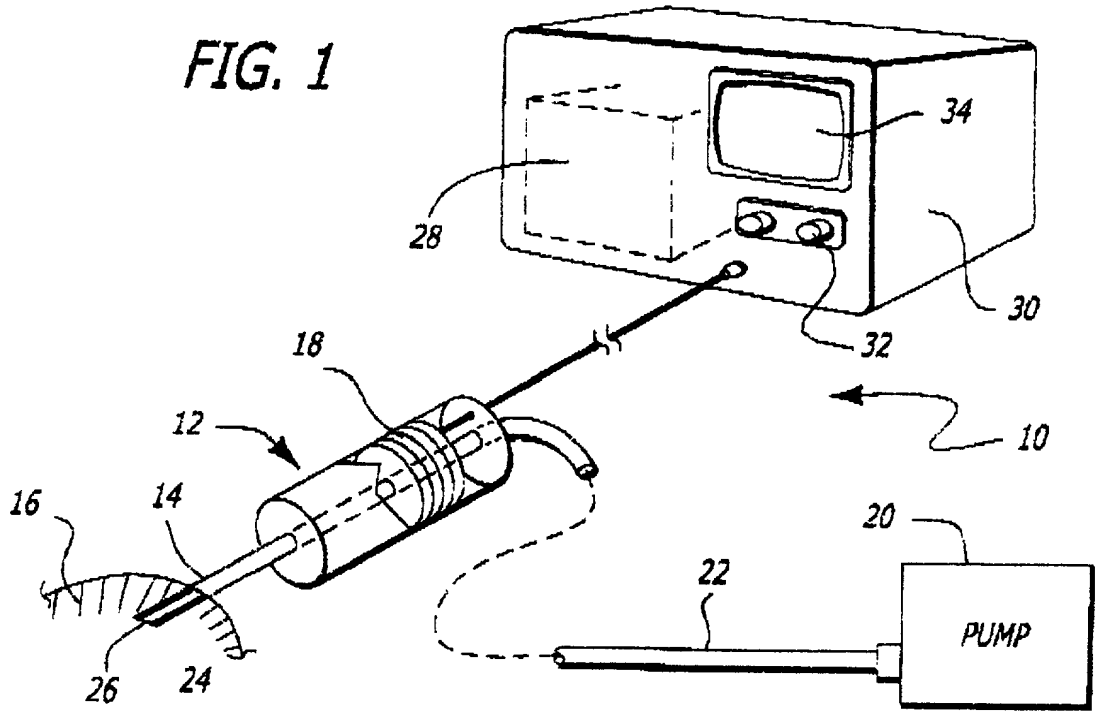
15. The method of claim 14, wherein the pulses are at a frequency at approximately the natural frequency of the transducer.

16. The method of claim 14, wherein each pause is of a duration to prevent a significant generation of heat by the cutting element.

ABSTRACT

A control circuit that provides a driving signal to a transducer coupled to a mechanical cutting element. The transducer is capable of operating in a resonant mode. The driving signal contains a plurality of pulses provided in a time interval that does not cause the transducer to operate in the resonant mode.

FIG. 1


34
28
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PUMP
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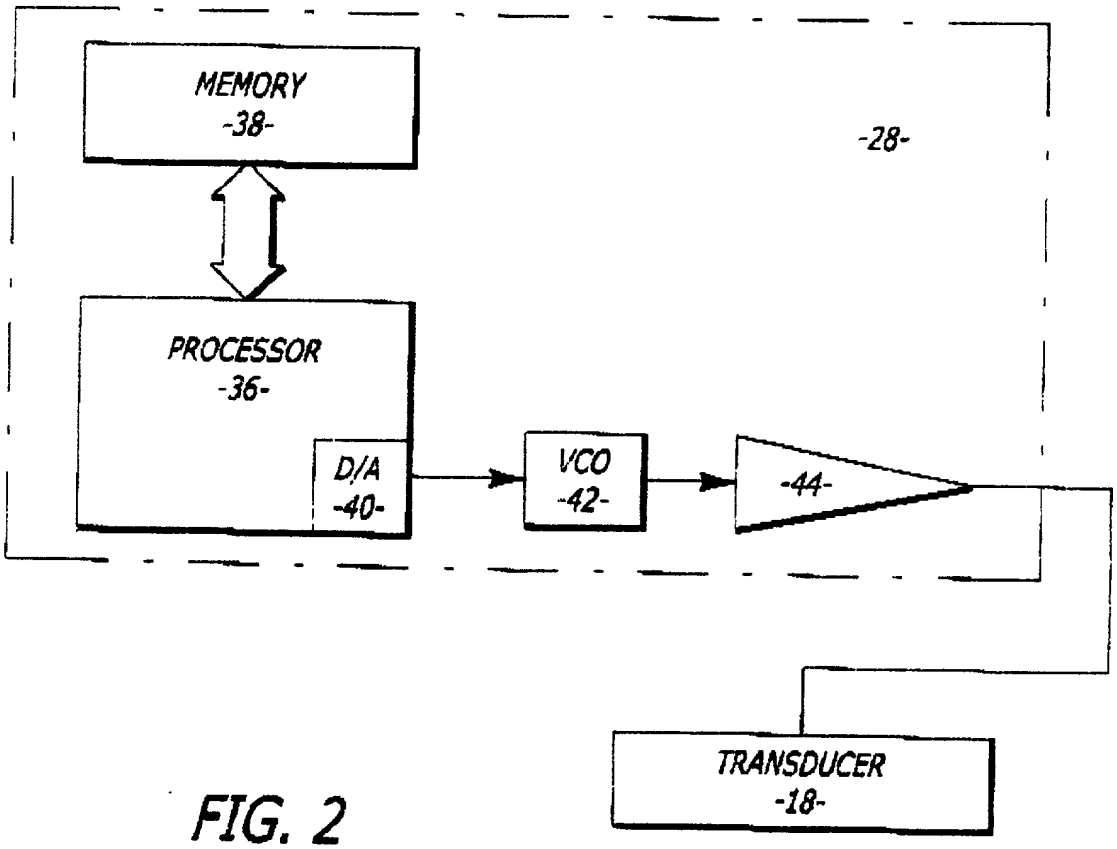
MEMORY
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-28-
PROCESSOR
-36-
D/A
-40-
VCO
-42-
-44-
TRANSDUCER
-18-

FIG. 2

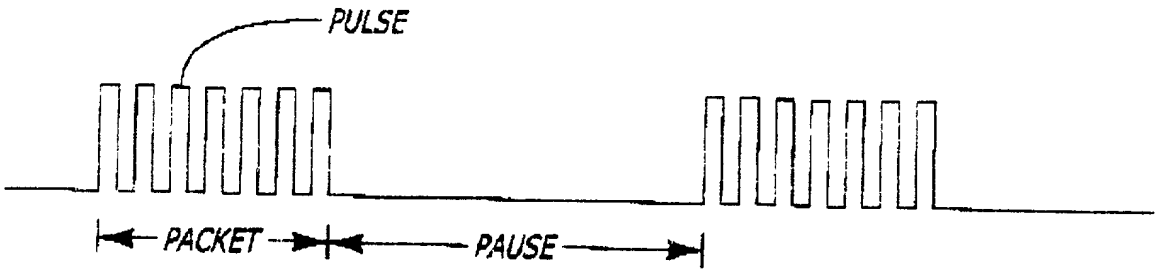

FIG. 3

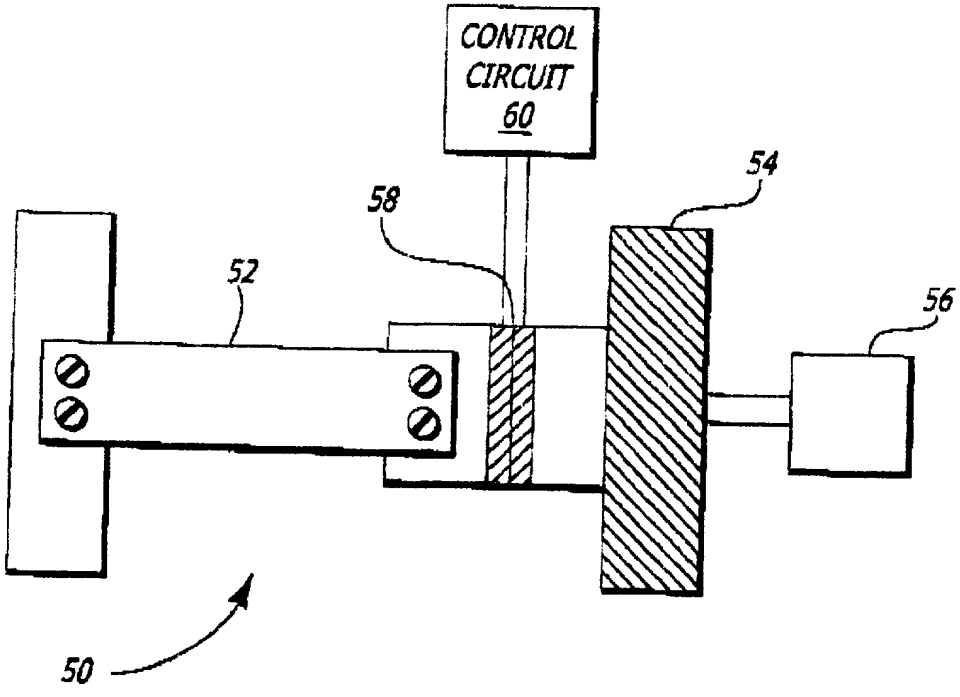

FIG. 4

DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below, next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or any original, first, and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled:

LOW FREQUENCY CATARACT FRAGMENTING DEVICE

the specification of which
- ☒ is attached hereto.
- ☐ was filed on _____ as
  United States Application Number _____
  or PCT International Application Number _____
  and was amended on _____
  (if applicable)

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claim(s), as amended by any amendment referred to above. I do not know and do not believe that the claimed invention was ever known or used in the United States of America before my invention thereof, or patented or described in any printed publication in any country before my invention thereof or more than one year prior to this application, that the invention was not published in an application filed before my invention, that the same was not in public use or on sale in the United States of America more than one year prior to this application, and that the invention has not been patented or made the subject of an inventor's certificate issued before the date of this application in any country foreign to the United States of America on an application filed by me or my legal representatives or assigns more than twelve months (for a utility patent application) or six months (for a design patent application) prior to this application.

I acknowledge the duty to disclose all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code, Section 119(a)-(d), of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Prior Foreign Application(s):

APPLICATION NUMBER	COUNTRY (OR INDICATE IF PCT)	DATE OF FILING (day, **month**, year)	PRIORITY CLAIMED UNDER 37 USC 119
			☐ No ☐ Yes
			☐ No ☐ Yes

I hereby claim the benefit under Title 35, United States Code, Section 119(e) of any United States provisional application(s) listed below:

APPLICATION NUMBER	FILING DATE
60/173,829	December 30, 1999

I hereby claim the benefit under Title 35, United States Code, Section 120 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, Section 112, I acknowledge the duty to disclose all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, Section 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application:

APPLICATION NUMBER	FILING DATE	STATUS (ISSUED, PENDING, ABANDONED)

I hereby appoint IRELL & MANELLA LLP, a firm including: Paul Backofen, Reg. No. 42,278; Norman E. Brunell, Reg. No. 26,533; Douglas Carsten, Reg. No. 43,534; Gary Frischling, Reg. No. 35,515; Benjamin Hattenbach, Reg. No. 41,820; Andrei Iancu, Reg. No. 41,862; Bruce D. Kuyper, Reg. No. 33,937; Soycon Laub, Reg. No. 39,266; Samuel K. Lu, Reg. No. 40,707; Kimberley G. Nobles, Reg. No. 38,255; Lisa Partain, Reg. No. 40,763; Babak Redjaian, Reg. No. 42,096; Flavio Rose, Reg. No. 40,791; David Rosman, Reg. No. 43,059; Peter Wied, Reg. No. 43,264; Sharon Wong, Reg. No. 37,760; and Ben J. Yorks, Reg. No. 33,609; my attorneys; with offices located at 840 Newport Center Drive, Suite 400, Newport Beach, California 92660, telephone (949) 760-0991, with full power of substitution and revocation, to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of First/Joint Inventor:
(given name, middle initial, family name) **Alex Urich**

Inventor's Signature Alex Urich Date 3/30/00

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Inventor's Signature Michael Curtis Date 3/30/00

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